EXHIBIT 7

Confidential: Subject to Protective Order

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK

Expert Report of Fengtian Xue, Ph.D.

December 22, 2022

It is also reported in Armarego (1996 (Edition 4th) 2009 (Edition 6th)) that "DMF decomposition is catalyzed by acidic and basic materials, so that even at room temperature, DMF is appreciably decomposed if allowed to stand for several hours with solid KOH, NaOH, CaH_2."[45] However, solid KOH, NaOH, CaH_2 represent strong bases, which create an unusually strong basic environment around the solid base themselves. In my opinion, the reaction condition of the crude Valsartan (step #4) in the $ZnCl_2$ process was neutral and is dramatically different from the strong basic conditions in the presence of solid bases KOH, NaOH, CaH_2. I have not seen evidence that acidic condition would catalyze the decomposition of DMF. During the quenching process of the $ZnCl_2$ process, the pH value was adjusted to [redacted][46] The solvent DMF is generally known to be stable under this weakly acidic condition.

B. Nitrosamine Formation From Tertiary Amines (TEA)

Distinct from secondary amines, reaction of tertiary amine with nitrosonium ion (NO^+) involves a much more complicated mechanism and the overall reaction, therefore, is dramatically slower.[47,48] As an example, formation of NDEA from TEA is detailed in **Figure 9**. TEA must first react with NO^+ (**4,** *see* **Figure 5**, above) to generate a nitroso-compound (**10**). The nitroso-compound (**10**) slowly eliminates a nitroxyl (HNO) molecule,[6,7] to generate the iminium chloride compound (**11**). Addition of a water molecule to the iminium ion (**11**) gives the hydroxylated intermediate (**12**), which then eliminates an acetaldehyde (**13**) to yield diethylamine (**5a**), a secondary amine that is analogous to dimethylamine (**5**, *see* **Figure 5**, above). Similar to dimethylamine **5**, diethylamine **5a** can be nitrosated by NO^+ (**4**) to finally produce the nitrosamine NDEA. Overall, the mechanism of NDEA formation from TEA takes four more steps than that of NDMA formation from dimethylamine.

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45 (Armarego (1996 (Edition 4th)), Page 206.

46 (ZHP02579969.)

47 Smith PAS, Loeppky RN. (1967). Nitrosative cleavage of tertiary amines. *J. Am. Chem. Soc.* 89, 1147-1157.

48 Smith PAS, Pars HG. (1959). Nitrosative cleavage of N',N'-dialkhylhydrazides and tertiary amines. *J. Org. Chem.* 24, 1325-1332.

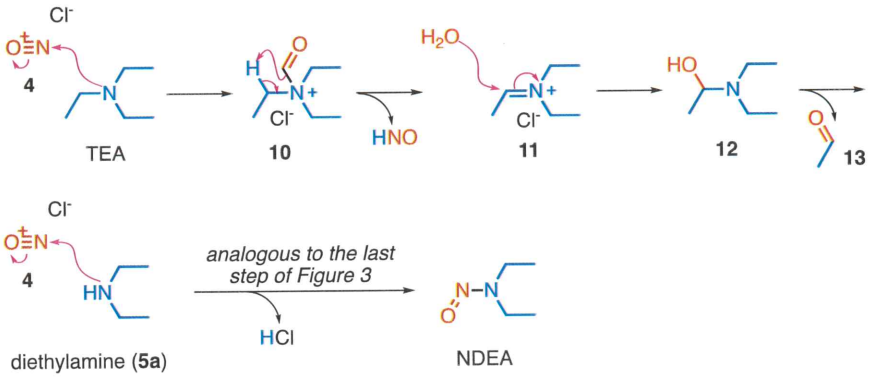

Figure 9. Mechanism for the formation of NDEA from nitrosonium ion (**4,** NO^+) and TEA.

The nitrosation reactions of tertiary amines (e.g., TEA) were far less known than those of secondary amines (e.g., dimethylamine and diethyamine). Historically, there has been argument as to whether tertiary amines react with nitrous acid.[49] A literature search related to the synthetic method to the production of NDEA from TEA on SciFinder[50] only generated 10 known publications. Common reactions are typically reported in tens of thousands of publications. Moreover, none of these journal articles addresses the use of nitrous acid (or sodium nitrite + inorganic acid) and TEA to produce NDEA. Instead, all the published methods included a special nitrosating reagent such as the Fremy's salt,[51] nitric acid/acetic anhydride,[52] N_2O_3,[53] and N_2O_4[54] to facilitate the formation of NDEA. It is worth noting that, at low pH, a tertiary amine (e.g., TEA)

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49 Hein GE. (1963) the reaction of tertiary amines with nitrous acid. J. Chem. Educ. 40(4):181.

50 SciFinder is produced by Chemical Abstracts Service (CAS). It is the most comprehensive database for the chemical literature. SciFinder can search by topic, author, substances (by name or CAS Registry Number). In addition, one can also use the editor feature to draw chemical structures, substructures, or reactions. SciFinder is a core research tool for chemistry, chemical engineering, materials science, and other science and engineering disciplines.

51 Castedo, Luis; et al, (1983) Fremy's salt (potassium nitrosodisulfonate): a nitrosating reagent for amines. 6, 301-302.

52 Boyer JH, Pillai TP, Ramakrishnan VT. (1985) Nitrosamines and nitramines from tertiary amines. Synthesis, 677-679.

53 Rosadiuk, Kristopher A.; et al, (2018) Isolable Adducts of Tertiary Amines and Dinitrogen Trioxide. European Journal of Inorganic Chemistry, 41, 4543-4549.

54 Boyer, Joseph H.; et al, (1985) Nitrosamines from tertiary amines and dinitrogen tetraoxide. Journal of the Chemical Society, Perkin Transactions 1: Organic and Bio-Organic Chemistry (1972-1999), (8), 1661-4; Iranpoor, Nasser; Firouzabadi, Habib; Pourali, Ali. (2005), Dinitrogen tetroxide-impregnated charcoal (N2O4/Charcoal). Selective nitrosation of amines, amides, ureas, and thiols. Synthetic Communication, 35(11), 1517-1526.

Signed on the 22nd day of December, 2022.

Fengtian Xue, Ph.D.